Gold Coast University Hospital (GCUH) - Trauma

Local Services Offered:
Clinical trials site;Investigator Initiated Trials;Satellite Site;Trial Patient Recruitment;Treatment of patients;Completion of study documentation as per ICH GCP and contract
Details: This PDF complements the information found in the CSV generated by this website with additional site information.

Facility Details:	
Please provide your Facility Website.	www.goldcoast.health.qld.gov.au/hospitals-and-centres/gold-coast-university-hospital
What Department is your Trial Site? (Queensland Health HHS- See List of Services and Levels-Clinical Services Capability Framework)	Medicine
Is your Facility affiliated with a government agency or part of a government funded health service?	Yes
Is your facility/organisation a Life Sciences Queensland (LSQ) Member?	No
Do you have Affiliated Research Sites or Satellite Sites/Clinics? *A Satellite Site is a secondary location where the investigator sees clinical trial subjects. Usually this is the same investigator who sees subjects at the primary site location.*	N/A
Other facility details	N/A
Provide the list of Sub-Therapeutic Areas for your Facility.	Trauma
Does your Clinical Trial site undertake any patient recruitment?	Yes
IRB/ERB/Ethics Committee:	
Does your Facility perform HREC (IRB/ERB/Ethics) Committee submissions?	Yes
Does your Facility have a dedicated department or group to perform HREC (IRB/ERB/ETHICS) Committee submissions?	No
Types of HREC (IRB/ERB/ETHICS) Committee that are used	Local;Central Acting as Local

What is the meeting frequency of your Local IRB/ERB/Ethics Committee?	Monthly, 2 per week with NMA
Does your Facility have other review boards that need to approve the study prior to HREC (IRB/ERB/Ethics) Committee submission? For example, scientific, radiation safety committees, or others.	No
Does the HREC Committee require payment prior to the release of final approval documents?	Yes
Consent:	
Does your Facility have a written SOP/Policy/Procedure for Informed Consent?	Yes
Does your Facility have a written SOP/Policy/Procedure for Minor Assent for paediatric populations?	Yes
Does your Facility have a written SOP/Policy/Procedure for Other vulnerable populations?	Yes
Does your Facility have access to translators and translation support for study conduct (e.g. consent, study-specific instruction)?	Yes
Training:	
Does your Facility have a training program for the research staff?	Yes
Does your Facility training course content include GCP?	Yes
If your facility uses external program course/s. Please provide the program course/s name.	IQVIA
Do you have a process or program in place to retrain research staff when a protocol is amended?	Yes
Facility And Equipment:	
Facility Capabilities:	
Is your Facility capable of administering infusions?	Yes
Can your Facility support in- patient admissions for research studies?	Yes

Can your Facility support patient visits on weekends?	Yes
Does your Facility have the ability to collect and store PK/PD specimens?	Yes
Does your Facility have the ability to collect PK/PD samples beyond normal business hours?	Yes
Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	Yes
Is your Facility adequately staffed to support studies with both blinded and unblinded Investigational Product?	Yes
Does the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)?	Yes
Equipment:	
Does your Facility have the necessary equipment to treat medical emergencies (for example crash/code cart)?	Yes
Does your Facility have an SOP or process that ensures routine calibration and maintenance of general equipment? Examples of general equipment include: scale, pulse oximeter, stadiometer, sphygmomanometer, etc.?	Yes
Please list any additional equipment.	Ultrasounds
IT Capabilities:	
Does your Facility have computers that are dedicated to research studies?	Yes
What type of computer operating system(s) does your institution use to support studies?	Windows (Windows XP; Windows 7; Windows 10; etc)
What browser does your facility use?	Edge
Does the Facility have access to local IT support?	Yes
Does your Facility limit or prohibit access and use of external web-based tools or sites for clinical research (E.g. web portals to submit documents to sponsors or CROs)?	Yes, CRA have read-only access

Please indicate all equipment that will be available to Monitors	Phone;Copy Machines;Internet Access
Labs:	
Does your Facility use a local lab?	Yes
Please provide the local lab details.	Pathology Queensland-Gold Coast
Does your Facility use a private lab service?	Yes
Please provide the private lab details.	SNP, QML
IP Storage Details:	
IP Recipient Name	Gold Coast University Hospital Pharmacy
Is the Investigational Product Storage Room secured with controlled access?	Yes
Does the Investigational Product Storage Room have Backup Power?	Yes
Does your facility have a written SOP/Policy/Procedure for the destruction of Investigational Product?	Yes
Does the Facility have the ability to handle radio-labelled Investigational Products?	Yes
Does your Facility have the ability to manage on-site or off- site destruction of controlled substances when appropriate?	Yes
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	Yes
Does your Facility have a written SOP/Policy/Procedure to ensure that Investigational Product is appropriately maintained during transportation to Satellite Site(s)?	N/A
Source Documents:	
Does your Facility have patient record archiving on-site?	Yes
Provide Location name and address of any offsite archives.	Grace
What Electronic Data Capture (EDC) systems has your Facility used for clinical trials?	Oracle Inform;Medidate Rave;Oracle Remote Data Capture (RDC); Auslab
Please provide other EDC Systems.	iMedidata; RedCap; IVRS/IWRS
Electronic Medical Records (EMR) /Electronic Health Records (EHR):	

Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	Yes
Please list any access limitations/requirements for the Electronic Medical Records.	Cerner ieMR Solution in use at site; includes PowerTrials; monitors require login profile to access the system. Onboarding of Clinical Informatics Specialist (Research) from October 2019.